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[10123/02801]

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Christopher T. DAVEY
Serial No.	:	09/556,102
Filed	:	April 21, 2000
For	:	VALVE INTRODUCER SHEATH AND RELATED METHODS
Group Art Unit	:	3763
Examiner	:	M. DeSanto

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By: _____
Patrick J. Fay, (Reg. No. 35,508)
Date: **March 19, 2004**

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Transmitted herewith please find three (3) copies of an Appeal Brief for filing in the above-identified application.

The Commissioner is hereby authorized to charge the Appeal Brief filing fee of $330 and any additional fees required to the Deposit Account of **Fay Kaplun & Marcin, LLP 50-1492**. A copy of this paper is enclosed for that purpose.

Respectfully submitted,

Dated: March 19, 2004

By: _____
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APPELLANT'S BRIEF ON APPEAL

This is an appeal from the Office Action dated August 26, 2003 finally rejecting all pending claims in the above-identified application, as further explained by the Advisory Action dated December 29, 2003.

The Final Rejection should be reversed because the derivation of the claimed invention from the cited references

following the teachings of the cited references alone would not have been obvious to the person of ordinary skill in the art at the time the invention was made. Rather, the Final Rejection is premised on an impermissible hindsight reconstruction of the prior art in light of Appellant's teachings.

The following sections of this brief are arranged in the order required by 37 C.F.R. §1.192 and M.P.E.P. §1206:

I. Real Party In Interest

An assignment of the above-identified application from the inventors to Scimed Life Systems, Inc. was recorded in the Patent Office at frame 0058 of reel 011088 on April 13, 2001. Thus, Scimed Life Systems, Inc. is the real party in interest in this appeal.

II. Related Appeals and Interferences

The undersigned representative of the applicant is not aware of any other appeal or interference which will directly affect, or be directly affected by or have a bearing on the Board's decision in this appeal.

III. Status of Claims

The claims pending in the case are claims 12-23, 25-34 and 36-45, all of which were under rejection and on appeal.[1]

Claims 12-23, 25-34 and 36-45 have been rejected under

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[1] A copy of claims 12-23, 25-34 and 36-45 is attached as Appendix A.

35 U.S.C. §103 as allegedly obvious over certain prior art.

IV. Status of Amendments

A Response to Final Rejection dated November 26, 2003 has been considered, but was not deemed to place the application in condition for allowance. (See 12/29/2003 Advisory Action). The claims presently pending are as Amended in the Amendment filed March 17, 2003 but apparently received by the Office on April 1, 2003. (See 4/23/03 Office Action).

V. Summary of Invention

The invention relates to an apparatus for facilitating the insertion of a flexible medical device into a body, comprising:

- a sheath comprising a proximal hub portion, an elongated body portion extending distally from the proximal hub portion, at least some of the elongated body portion capable of being placed into the body, a passageway extending through the proximal hub and elongated body portions, the passageway being defined by an inner surface of the sheath, and a pair of lines extending at least some of the length, and on opposite sides, of the sheath, at least the sheath being separable along the lines; and

- a valve comprising a foam material filling at least some of the length of the passageway in the elongated body portion, the length of the foam material within the passageway being greater than the width of the foam

material at any point within the passageway, and one or more self-sealing slits in the foam material, none of the slits extending in width to the inner surface of the sheath, the one or more slits capable of allowing the flexible medical device to pass therethrough and sealing around the device.

VI. Issues

Whether the medical apparatuses of claims 12-23, 25-39 and 36-45 are unpatentable under 35 U.S.C. § 103 as obvious over Walker et al. (U.S. Patent No. 5,755,693) in view of Deem et al. (U.S. Patent No. 5,104,389).

VII. Grouping of Claims

Each of claims 12 and 14-23 stands with independent claim 13. Each of claims 25 and 27-34 stands with independent claim 26. Each of claims 36-38 and 40-45 stands with independent claim 39.

VIII. Argument

The substantive issues on this appeal are:

1. Whether the medical apparatuses of claims 12-23, 25-34 and 36-45 are unpatentable under 35 U.S.C. § 103 as obvious Walker et al. (U.S. Patent No. 5,755,693) in view of Deem et al. (U.S. Patent No. 5,104,389).

It is respectfully submitted that this rejection is in

error and must be reversed because the references fail to suggest the claimed elements and they provide no motivation to a person of ordinary skill in the art to combine the teachings of the references in order to produce a medical device as recited in any of claims 12-23, 25-34 and 36-45 of the present application.

It is well established that, for a claim to be unpatentable as obvious:

1. The prior art must suggest the desirability of doing what an applicant has done. Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1271, 20 U.S.P.Q. 2d 1746, 1751 (Fed. Cir. 1991).

2. It is improper, therefore, to engage in a hindsight reconstruction of a claimed invention using an applicant's disclosure as a template and selecting elements from the prior art to fill the gaps. In re Gorman, 933 F.2d 982, 987, 18 U.S.P.Q. 2d 1885, 1888 (Fed. Cir. 1991).

3. Put another way, it is improper to modify a prior art reference unless the prior art suggests the desirability of the modification. In re Gordon, 733 F.2d 900, 902, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984). It also is improper to pick and choose from a reference only those parts which support the rejection to the exclusion of other portions which do not. Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., 796 F.2d 443, 448, 230 U.S.P.Q. 416, 419 (Fed. Cir. 1986). Teachings of a reference which lead away from Appellant's

invention are part of the reference and must be considered. In re Mercier, 575 F.2d 1151, 1165, 185 U.S.P.Q. 774, 778 (C.C.P.A. 1975).

4. It is insufficient that the prior art disclosed the components of the patented device, either separately or used in other combinations; there must be some teaching, suggestion or incentive to make the combination made by the inventor. Northern Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 934 (Fed. Cir. 1991).

5. The nature of the problem which persisted in the art and the inventor's solution are factors to be considered in determining whether the invention would have been obvious to a person of ordinary skill in the art. Northern Telecom, supra., at 908 F.2d 935.

6. A combination invention is not obvious simply because each of its elements is found in different prior art references. It is improper to pick and choose among the individual elements of different references to recreate the claimed invention. SmithKline Diagnostics, Inc. v. Helena Laboratories Corp., 859 F.2d 878, 886-87, 8 U.S.P.Q. 2d 1468, 1475 (Fed. Cir. 1988). The suggestion for making an applicant's combination must come from the prior art, Carella v. Starlight Archery and Pro Line Co., 804 F.2d 135, 140, 231 U.S.P.Q. 644, 647 (Fed. Cir. 1986), and not from applicant's specification. In re Vaeck, 947 F.2d

488, 493, 20 U.S.P.Q. 2d 1438, 1442 (Fed. Cir. 1991). There must be some reason for the combination other than hindsight gleaned from applicant's specification. Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143, 227 U.S.P.Q. 543, 551 (Fed. Cir. 1985).

7. Not only must the prior art suggest doing what an applicant claims, but the prior art, not applicant's disclosure, must provide both the suggestion and a reasonable expectation of success. In re Vaeck, supra., at 947 F.2d 993, 20 U.S.P.Q. 2d at 1442. Accordingly, neither "obvious to try" nor "obvious to experiment" is the standard for obviousness. Akzo NV v. E.I. dupont denemours, 810 F.2d 1148, 1 U.S.P.Q. 2d 1704, 1707 (Fed. Cir. 1987); In re Dow Chemical Co., 837 F.2d. 469, 473, 5 U.S.P.Q. 2d 1529, 1531 (Fed. Cir. 1988).

The Final Rejection fails to conform to the foregoing principles. It fails to establish that the references relied upon, taken separately or in combination, suggest to a person of ordinary skill in the art an apparatus as Appellant claims. Rather, the Final Rejection has improperly used Appellant's disclosure as a template, has selected bits and pieces from the references with the benefit of hindsight, and has disregarded evidence supporting patentability.

1. The References

The Final Rejections of claims 12-23, 25-34 and 36-45

are based upon art references:

(1) Walker et al. (U.S. Patent No. 5,755,693); and

(2) Deem et al. (U.S. Patent No. 5,104,389).

As will be discussed further below, the Examiner has rejected claims 12-23, 25-34 and 36-45 under 35 U.S.C. § 103 as obvious over Walker et al. in view of Deem et al.

a. Walker et al.

Walker et al. ("Walker") purports to show an apparatus for bloodless insertion and withdrawal from a patient's body comprising a sealing structure formed at a proximal end thereof. The sealing structure is described in each embodiment as a deformable, elastomeric material, which is biased shut. A longitudinal member (i.e. needle, cannula, probe) can be inserted through at least one slot in the sealing structure. In every embodiment shown, at least one slot extends to the periphery of the sealing structure. The drawings show each embodiment of the sealing structure as a cylindrical object, without mention of any relationship between diameter, length or width.

b. Deem et al.

Deem et al. ("Deem") purports to show a catheter introducer which comprises a valve for receiving an elongated member. The valve is described as comprising an elastomeric partition member, which is an elastomer wall, coupled to a foamed elastomer material. The elastomeric wall has a series of slits, which do not pass through the foamed elastomeric layer, that

allow an elongated member to advance into the foamed elastomeric material. The elastomeric wall and foamed elastomeric layer are not described dimensionally in the specification, and the drawings simply show an undefined cylindrical object without any reference to height, width or diameter.

2. The Apparatus of Claims 12-23, 25-34 and 36-45 is Not Obvious Over Walker in view of Deem

It is respectfully submitted that appellant's apparatus as recited in claims 12-23, 25-34 and 36-45 is not obvious over Walker in view of Deem as indicated by the Examiner. The Examiner stated, in support of the rejections, that Walker discloses all limitations of claims 12-23, 25-34 and 36-45 except for the feature that none of the slits extend in width to the inner surface of the sheath, but that Deem discloses such a feature.

Claim 13 recites an apparatus for facilitating insertion of a flexible medical device into a body lumen comprising an elongated body portion and a valve including foam material filling at least some of the length of a passageway of the elongated body portion, wherein a "length of the foam material [of the valve] within the passageway being greater than the width of the foam material at any point within the passageway." The valve is also recited as including "one or more self-sealing slits in the foam material, none of the slits extending in width to the inner surface of the sheath." Claims 26 and 39 recite similar claim elements and, it is respectfully submitted, are allowable for the same reasons.

The Examiner has agreed that Walker shows no such slits and it is respectfully submitted that Deem also includes no

disclosure of a valve with slits where none of the slits extends to an inner surface of the sheath. The only discussion of the extent of the slits through the foam of Deem is in regard to a longitudinal direction (i.e., along a longitudinal axis of the valve and not radially) (in regard to partition member 24). That is, a valve according to one embodiment is described as including slits that do not pass all the way through the valve longitudinally. This is the only embodiment described as including slits, none of which pass all the way through the foam. There is no reference to the extent of any of these slits in the radial direction. Specifically, that the extent of the slits penetration of the foam is discussed only in the longitudinal direction is made clear in col. 6, lines 1 - 7 of the specification, wherein it is stated that Figs. 3 and 4 show opposed sides (opposed longitudinally) of the partition member 24 where the slit 40 does not extend all the way therethrough.

The Examiner responded to this argument by stating that Walker shows slits not extending to an inner surface of the sheath in Fig. 8, ref. 32. (See 8/26/03 Office Action, page 4, para. 4). However, this is clearly contradicted by the Examiner's own assertion on page 2 of the same Office Action that Walker "fails to discloses [sic] wherein none of the slits extend in width to the inner surface of the sheath." (Id., page 2, para. 2). In the Advisory Action, the Examiner reaffirmed his statement from the 8/26/03 Office Action, that Walker "has some slits that do not reach the inner sheath, but not all," and does not read on claim 13. (See 12/29/03 Advisory Action, page 2, para. 1). The Examiner stated, as grounds for the rejection, that Walker failed to show this very element and supplied Deem as an additional reference to make up this deficiency. The Examiner has maintained his position with respect to the Deem reference,

as noted in the Advisory Action. However, it is respectfully submitted that the response to the Applicant's arguments concedes that Deem fails to cure the deficiency.

In any case, it is respectfully submitted that even Fig. 8 of Walker fails to show this claim element. Claim 13 does not require that all slits penetrate through the foam to the sheath. Rather, this claim recites that "none of the slits [extends] in width to the inner surface of the sheath." Thus, although reference numeral 32 does show slits some of which do not penetrate all the way through the foam to the sheath, the is a large slit between the semi-circular halves of the valve 30C extends across the entire diameter of the valve in a manner completely opposed to the recited arrangement. Reference numeral 32 is used again in Fig. 9 of Walker to designate a single slit that extends across the entire valve 30D. Hence, when the two halves 30D are united, there will be a single slit 32 extending across the entire diameter of the valve. The relevant disclosure in Walker that describes reference numeral 32 is found in col. 7, lines 12-19, where the description reads, "opening 32 is defined by the facing abutting surfaces of two semi-circular elastomeric members which together comprise a sealing structure 30." Additionally, every figure in Walker that presents a clear view of the sealing structure, noticeably shows at least one slit that extends in width to the inner surface of the sheath. (See Walker '693, Figs. 4, 5-9, 11, 12, 16-16c, and 23-25). Particularly, with respect to Fig. 12, the description reads, "sealing structure 30 includes a slit 74 which extends to the periphery 34 of the sealing structure 30F."

Furthermore, the Examiner has pointed to Fig. 9 and col. 7, lines 37 - 43 as showing a valve wherein a "length of the

foam material [of the valve] within the passageway [is] greater than the width of the foam material at any point within the passageway," as recited in claim 13. However, it is respectfully submitted that these lines and the entire description make no mention of a relationship between a longitudinal length of the foam and its width. In fact, this portion of Walker simply states that the valve of Fig. 9 is longer longitudinally than the valve shown in Fig. 6.

In addition, the Examiner has pointed to Fig. 1 and the corresponding description in col. 5, lines 6 - 14 of Deem as showing the recited relation between the longitudinal length and width of the valve. However, it is respectfully submitted that this description refers to the length and width of element 27 which is simply a foamed elastomer material with no slits extending therethrough. Specifically, Deem shows a valve including a first, solid, hydrophilic elastomer wall bonded to a foamed elastomer. The foam portion 27 of the valve of Deem includes no slits extending therethrough. Thus, it is respectfully submitted that Deem does not show a valve including a foam material filling at least a portion of the length of a passageway with "one or more self sealing slits in the foam material," as recited in claim 13. Specifically, Deem states that, if desired, the *partition member* may define a reclosable aperture such as a slit to further facilitate penetration of the elongated member through the partition member. (See Deem '389, col. 2, lines 42-54). However, no slits are described or suggested in any foam material.

The Advisory Action restates the Examiner's grounds for the rejection with regard to Deem. The motivation to combine, the Examiner asserts, is shown in Figure 5 and col. 2, lines 42-

54. Fig. 5 includes a series of horizontal, parallel lines which appear to be shadings to illustrate the cylindrical nature of the foam material. However, there is absolutely no written description of the arrangement of Fig. 5, which makes the structure depicted at reference numeral 40 equivocal and indiscernible. Thus, it is respectfully submitted that whatever may or may not be shown in this Figure is unclear and insufficient to support an obviousness rejection. Hence, it is respectfully submitted that inferences drawn from the drawing of Fig. 5 are ambiguous, at best, and should not be relied upon.

The disclosure that the Examiner points to as suggesting the motivation to combine is specifically directed at the partition member in Deem. (See Deem '389, col.2, lines 42-54). Deem clearly intends to distinguish its partition member from the foam material. (See, Id. at col. 2, lines 24-26) ("The inner face of the elastomer wall is bonded to a foamed elastomer material...."). The description clearly states that the partition member may define a slit. However, there is no disclosure that would suggest that the slit of the partition member extends completely through the partition member and into the foam material. Particularly, Deem states, "blood is prevented from passage into the foamed elastomer material from the inner end of the hemostasis valve, except possibly for minor leakage *through a slit or the like formed through the partition member.*" (Id. at col. 3, lines 44-48) (emphasis supplied). In further detail and with reference to Fig. 4, an elongated member can penetrate "through the foamed material 27 without use of a slit." (Id. at col. 6, lines 6-7). It is respectfully submitted that any conclusions drawn in regard to the particular arrangement of any slit portions of the valve besides the partition member are purely speculative and insufficient to

support the §103 rejection.

Thus, it is respectfully submitted that neither Walker nor Deem shows a valve comprised of a foam filling at least a portion of the length of a passageway with "a length of the foam in the passageway being greater than a width of the foam material at any point within the passageway" in combination with "one or more self-sealing slits in the foam material, none of the slits extending in width to the inner surface of the sheath," as recited in claim 13.

Similarly, it is respectfully submitted that neither Walker nor Deem shows a valve comprised of a foam filling at least a portion of the length of a passageway with "a length of the foam material in the passageway being greater than a width of the foam material at any point within the passageway" as recited in claims 26 and 39.

It is therefore respectfully submitted that claim 13 is not rendered obvious by Walker and Deem either taken alone or in combination and that this rejection should be withdrawn.

In addition, as stated previously there is ample legal authority for the proposition that the prior art must suggest the desirability of doing what an applicant has done. Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1271, 20 U.S.P.Q. 2d 1746, 1751 (Fed. Cir. 1991) and it is improper, therefore, to engage in a hindsight reconstruction of a claimed invention using an applicant's disclosure as a template and selecting elements from the prior art to fill the gaps. In re Gorman, 933 F.2d 982, 987, 18 U.S.P.Q. 2d 1885, 1888 (Fed. Cir. 1991). Put another way, *it is improper to modify a prior art reference unless the*

prior art suggests the desirability of the specific modification. In re Gordon, 733 F.2d 900, 902, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984). The suggestion for making an applicant's combination must come from the prior art, Carella v. Starlight Archery and Pro Line Co., 804 F.2d 135, 140, 231 U.S.P.Q. 644, 647 (Fed. Cir. 1986), and not from applicant's specification. In re Vaeck, 947 F.2d 488, 493, 20 U.S.P.Q. 2d 1438, 1442 (Fed. Cir. 1991). There must be some reason for the combination other than hindsight gleaned from applicant's specification. Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143, 227 U.S.P.Q. 543, 551 (Fed. Cir. 1985).

As described above, Deem shows no slits in any foam material and therefore provides absolutely no motivation to one of skill in the art to alter the design of slits in the foam of Walker. The Examiner agrees that the rejection was based on hindsight, but states that this hindsight reconstruction of the invention is proper because it takes into account only knowledge which was within the level of ordinary skill in the art at the time. However, the Examiner gives no specific indication of what knowledge he is assuming for those of skill in the art, nor does he indicate how any such knowledge makes this hindsight reconstruction allowable. The Examiner goes on to state further cases in support of the proposition that it is proper to take into account inferences ones skilled in the art would have drawn from the cited references. However, the Examiner likewise fails to show any specific instance of an application of this rule. Thus, it is respectfully submitted that this rejection is based on an improper hindsight reconstruction of the invention as well as vague and unsupported statements about the meaning of the references to those skilled in the art which are used to prop up deficiencies in the references with respect to various claim

elements.

Furthermore, as stated previously, it is respectfully submitted that all of the embodiments of Walker are shown with at least one slit that does extend through the entire width of the foam valve because this feature aids in the splitting of the sheath and its removal from the catheter while leaving the catheter in place within the body. Thus, without specific motivation for a change to a fundamental feature of the invention, it is respectfully submitted that one of ordinary skill in the art would not have been motivated to depart from the teaching of Walker and would not have drawn the inferences hinted at by the Examiner.

For these reasons it is respectfully submitted that claims 13, 26 and 39 are not rendered obvious by Walker and Deem either taken alone or in combination and that this rejection should be withdrawn. Because claims 12, 14 - 23, 25, 27 - 34, 36 - 38 and 40 - 45 depend from and, therefore, include all of the limitations of one of claims 13, 26 and 39, it is submitted that these claims are also allowable.

IX. Conclusion

It is respectfully submitted that appellant has demonstrated that the subject matter of claims 12-23, 25-34 and 36-45 is not obvious in light of the cited art, taken alone or in combination. Thus, it is respectfully requested that the Examiner's final rejection of claims 12-23, 25-34 and 36-45 be reversed and all appealed claims found patentable.

Respectfully submitted,

Dated: March 19, 2004

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APPENDIX A - PENDING CLAIMS

12. The apparatus of claim 13 wherein the foam material includes a proximal section and a distal section, the one or more slits in the distal section remaining sealed as the flexible medical device is introduced first into the one or more slits in the proximal section.

13. Apparatus for facilitating the insertion of a flexible medical device into a body, comprising:

(a) a sheath comprising

a proximal hub portion,

an elongated body portion extending distally from the proximal hub portion, at least some of the elongated body portion capable of being placed into the body,

a passageway extending through the proximal hub and elongated body portions, the passageway being defined by an inner surface of the sheath, and

a pair of lines extending at least some of the length, and on opposite sides, of the sheath, at least the sheath being separable along the lines; and

(b) a valve comprising

a foam material filling at least some of the length of the passageway in the elongated body portion, the length of the foam material within the passageway being greater than the width of the foam material at any point within the passageway, and

one or more self-sealing slits in the foam material, none of the slits extending in width to the inner surface of the sheath, the one or more slits capable of allowing the flexible medical device to pass therethrough and sealing around the device.

14. The apparatus of claim 13 wherein the lines comprise scorings.

15. The apparatus of claim 13 wherein the valve is separable with the sheath.

16. The apparatus of claim 15 wherein the valve that is separable is splittable into two halves along one of the self-sealing slits.

17. The apparatus of claim 13 wherein the elongated body portion comprises at least a first section and a second section, a first cross-sectional area of the first section being greater than a second cross-sectional area of the second section.

18. The apparatus of claim 17 further comprising a shoulder disposed within the passageway and between the first and second sections.

19. The apparatus of claim 12 wherein the foam material defines a depression in the proximal section.

20. The apparatus of claim 19 wherein the foam material defines the depression which comprises a conical shape for receiving the flexible medical device.

21. The apparatus of claim 13 wherein the proximal hub portion comprises a pair of wings extending substantially perpendicular to the elongated body portion of the sheath.

22. The apparatus of claim 13 wherein the foam material comprises a closed cell foam.

23. The apparatus of claim 13 wherein the foam material is affixed to a portion of an inner surface of the sheath that defines the passageway.

25. The apparatus of claim 26 wherein the foam material includes a proximal section and a distal section, the one or more slits in the distal section remaining sealed as the flexible medical device is introduced first into the one or more slits in the proximal section.

26. An apparatus for facilitating the insertion of a flexible medical device into a body, comprising:

(a) a sheath comprising

a proximal hub portion,

an elongated body portion extending distally from the proximal hub portion, at least some of the elongated body portion capable of being placed into the body,

a passageway extending through the proximal hub and elongated body portions, the passageway being defined by an inner surface of the sheath, and

a pair of lines extending at least some of the length, and on opposite sides, of the sheath, at least the sheath being separable along the lines; and

(b) a valve comprising

a foam material filling at least some of the length of the passageway in the elongated body portion, the length of the foam material within the passageway being greater than the width of the foam material at any point within the passageway, the foam material being affixed to a portion of the inner surface of the sheath, and

one or more self-sealing slits in the foam material, the one or more slits capable of allowing the flexible medical device to pass therethrough and sealing around the device.

27. The apparatus of claim 26 wherein the lines comprise scorings.

28. The apparatus of claim 26 wherein the valve is separable with the sheath.

29. The apparatus of claim 28 wherein the valve that is separable is splittable into two halves along one of the self-sealing slits with each of the halves of the valve remaining affixed to the respective halves of the sheath.

30. The apparatus of claim 26 wherein none of the one or more self-sealing slits in the foam material extend in width to the inner surface of the sheath.

31. The apparatus of claim 25 wherein the foam material defines a depression in the proximal

section.

32. The apparatus of claim 31 wherein the foam material defines the depression which comprises a conical shape for receiving the flexible medical device.

33. The apparatus of claim 26 wherein the proximal hub portion comprises a pair of wings extending substantially perpendicular to the elongated body portion of the sheath.

34. The apparatus of claim 26 wherein the foam material comprises a closed cell foam.

36. The apparatus of claim 39 wherein the foam material includes a proximal section and a distal section, the one or more slits in the distal section remaining sealed as the flexible medical device is introduced first into the one or more slits in the proximal section.

37. The apparatus of claim 39 wherein none of the one or more self-sealing slits extends in width to an inner surface of the sheath that defines the passageway.

38. The apparatus of claim 39 the one or more self-sealing slits substantially prevent the flow of gas into the passageway of the sheath.

39. Apparatus for facilitating the insertion of a flexible medical device into a body, comprising:

(a) a sheath comprising

a proximal hub portion,

an elongated body portion extending distally from the proximal hub portion,

a passageway extending through the proximal hub and elongated body portions, and

a pair of lines extending at least some of the length, and on opposite sides, of the sheath, at least the sheath being separable along the lines; and

(b) a valve comprising

an injected foam material filling at least some of the length of the passageway in the elongated body portion, the length of the foam material within the passageway being greater than the width of the foam material at any point within the passageway, and

one or more self-sealing slits in the foam material, the foam material and the one or more slits serving as a valve in the passageway of the sheath.

40. The apparatus of claim 39 wherein the lines comprise scorings.

41. The apparatus of claim 39 wherein the valve is separable with the sheath.

42. The apparatus of claim 39 wherein the foam material defines a depression in the proximal section.

43. The apparatus of claim 42 wherein the foam material defines the depression which comprises a conical shape for receiving the flexible medical device.

44. The apparatus of claim 39 wherein the proximal hub portion comprises a pair of wings extending substantially perpendicular to the elongated body portion of the sheath.

45. The apparatus of claim 39 wherein the foam material comprises a closed cell foam.